

REMARKS

A. Comparison to Applicants' Proposed Amendment After Final

In response to the final Office Action, Applicants filed a proposed amendment on August 10, 2005. The Advisory Action indicated that amendment would not be entered since, in the opinion of the Examiner, it raised new issues;

This Amendment is identical to the proposed amendment after final in the following respects:

- Method claims are canceled.
- Claim 18 is amended to add a “whereby clause”.

This Amendment differs from the proposed amendment after final in the following respects:

- Claim 18 is amended to add additional clarifying structure.
- New claims 34 and 35 are added.

B. Orientation Of Greater Compliance Was Raised But Apparently Not Clearly Considered

Claim 18 (as presented on May 3, 2005) calls for a specific orientation of the directional compliance with respect to the structure of the device. Specifically, the last clause of Claim 18 recited “said material oriented on said jacket with said first direction [i.e., direction of greatest compliance] extending in a direction substantially aligned with said longitudinal dimension [i.e., dimension defined between the base end and apex end of the jacket corresponding with the longitudinal dimension of the heart].” The present amendment also recites the orientation of the less compliant direction of the material as well as additional clarifying structure.

As noted in Applicants' May 3, 2005 remarks, “With respect to each of Alfernness, Shibamoto and McMurray, claim 1 is amended to reflect the structure that the jacket is more compliant in a longitudinal direction than in a circumferential direction. Namely, in response to any given force, the jacket stretches more longitudinally than circumferentially. No such structure is taught in the cited references.”

In the July 14, 2005 Office Action, this issue does not appear to be clearly addressed. While Applicants are not certain the Examiner is referring to this feature, the Examiner states:

1. With respect to McMurray, “The net is inherently capable of having material oriented with respect to the heart as claimed.” (7/14/05 Office Action, p. 3). No reference is made of any teaching or suggestion in McMurray of aligning a more compliant orientation of a fabric with a longitudinal axis of a jacket. Applicant

also notes the Examiner has not referenced any support for this claim of inherency. M.P.E.P. Sec. 2112.

2. With respect to Shibamoto, the Examiner states Shibamoto exhibits “different expansion in response to forces applied in different directions” (p. 4), but does not identify any teaching or suggestion in Shibamoto of aligning a more compliant orientation of a fabric with a longitudinal axis of a jacket. In fact, Shibamoto teaches the opposite orientation (i.e. more stretchable crosswise than lengthwise – col. 1, line 66).
3. With respect to Alferness, the Examiner states “[i]t is the examiner’s position that an open knit would exhibit different expansion in responses to forces in different direction.” While Applicants do not agree with this remark, Applicants note that with respect to Alferness (as with Shibamoto), the Examiner does not identify any teaching or suggestion in Alferness of aligning a more compliant orientation of a fabric with a longitudinal axis of a jacket.

C. Capability Of Aligning Material As Claimed Is Not Anticipation

In view of the above, even though the Examiner states the materials of the cited art would exhibit differential compliance, the Examiner’s only remarks regarding the orientation of the material to align the high compliance direction with the longitudinal axis of the jacket is the remark with respect to McMurray. Namely, “The net is inherently capable of having material oriented with respect to the heart as claimed.” (7/14/05 Office Action, p. 3). (Emphasis added).

This is not a proper basis for rejection of a claim as anticipated. McMurray and the other references do not teach or suggest such an orientation. Only Applicants teach a specific orientation.

The Examiner’s basis for rejection (“inherently capable”) has long been recognized as an improper basis for rejection. “In *Clough v. Gilbert & Barker Mfg.* (1882) [106 U.S. 166], the Supreme Court held that prior devices capable of being adjusted so as to operate in the same manner as the patented device did not anticipate.” Chisum, Patents, Vol. 1, § 3.03[1][b] (emphasis added).

D. The Claimed Orientation Has Significant Therapeutic Benefit

Orientation for greater compliance between the base end and apex end permits natural and unimpeded shortening of the axial length of the heart during filling while retaining the

desired benefit of presenting a load on the circumferential expansion of the heart. Also, such directional compliance can encourage the heart to re-shape from a diseased spherical shape to a more ellipsoid shape more commonly associated with a healthy heart. The invention as claimed lessens interference longitudinal function of the heart. The benefits of this aspect of Applicants' invention have been confirmed by recent scientific research. "Worsening global diastolic dysfunction of the left ventricle is associated with a progressive decline in longitudinal systolic function." Vinereanu, et al., "'Pure' Diastolic Dysfunction Is Associated With Long-Axis Systolic Dysfunction. Implications For The Diagnosis And Classification Of Heart Failure", European Journal of Heart Failure, Aug: 7(5): 820-8 (2005) (Emphasis added).¹

These benefits and structure to achieve these benefits are not shown or suggested by the references.

E. Added Amendment

With entry of this amendment, a "whereby" clause is added clarifying the consequences of the previously claimed orientation.

Applicants respectfully submit that entry of this amendment places this application in condition for allowance. Consideration, entry of this amendment and notice of allowance are solicited. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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¹ For the Examiner's convenience, Applicants attach a copy of PubMed web page containing the abstract of the Vinereanu article.



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1: Eur J Heart Fail. 2005 Aug;7(5):820-8.

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FULL-TEXT ARTICLE

"Pure" diastolic dysfunction is associated with long-axis systolic dysfunction. Implications for the diagnosis and classification of heart failure.

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AIMS: To investigate regional systolic function of the left ventricle, to test the hypothesis that "pure" diastolic dysfunction (impaired global diastolic filling, with a preserved ejection fraction $>/=50\%$) is associated with longitudinal systolic dysfunction. **METHODS AND RESULTS:** One hundred thirty subjects (31 patients with asymptomatic diastolic dysfunction, 30 with diastolic heart failure, 30 with systolic heart failure; and 39 age-matched normal volunteers) were studied by conventional and tissue Doppler echocardiography. Global diastolic function was assessed using the flow propagation velocity, and by estimating left ventricular filling pressure from the ratio of transmural E and mitral annular E(TDE) velocities (E/E(TDE)); and global systolic function by measurement of ejection fraction. Radial and longitudinal functions were assessed separately from posterior wall and mitral annular velocities. Global and radial systolic function were similar in patients with "pure" diastolic dysfunction and normal subjects, but patients with either asymptomatic diastolic dysfunction or diastolic heart failure had impaired longitudinal systolic function (mean velocities: $8.0+/-1.2$ and $7.7+/-1.5$ cm/s, respectively, versus $10.1+/-1.5$ cm/s in controls; $p<0.001$). In subjects with normal ejection fraction, global diastolic function correlated with longitudinal systolic function ($r=0.56$ for flow propagation velocity, and $r=-0.53$ for E/E(TDE) ratio, both $p<0.001$), but not with global systolic function. **CONCLUSION:** Worsening global diastolic dysfunction of the left ventricle is associated with a progressive decline in longitudinal systolic function. Diastolic heart failure as conventionally diagnosed is associated with regional, subendocardial systolic dysfunction that can be revealed by tissue Doppler of long-axis shortening. Diagnostic algorithms and definitions of heart failure need to be revised.

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